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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,847	12/08/2000	Liang C. Dong	ARC 2644 R1	2029

30766 7590 03/28/2008

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EXAMINER	
FAY, ZOHREH A	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
03/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/733,847	DONG ET AL.	
	Examiner	Art Unit	
	ZOHREH A. FAY	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *59-63,69-72 and 81-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *59-63, 69-72, 81-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 10, 2007 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 59, 61-63, 69-72 and 81-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudnic et al. (US 5,952,004) in view of Eckenhoff et al. (US 4,692,326) and further in view of Al-Razzak et al. (US 5,559,158).

Rudnick et al. disclose stable, drug delivery systems for poorly soluble active agents including HIV protease inhibitors, surfactant (col 6, line 1-5). The formulations are administered in capsules, such as controlled release soft gelatin capsules or tablet (col 7, lines 20-55). Patent 004 does not teach how the capsules are configured to release the formulation over the controlled period of time and whether there is a bilayer located within the drug and expandable layer. Patent 004 also does not teach the use of the claimed specific antiviral agent in a capsule form in combination with the secondary components. Ekenhoff et al. discloses controlled release oral capsules semipermeable wall for delivery of beneficial agent (col 4, line 50-60 and col 6, line 1-8). The capsule is configured with osmogent and polymer material that is water swellable (col 10, line 15-55) and (col 11, line 5-25). According to Ekenhoff et al., the capsule has inner layer and plug (gelatin) that are polymeric, contains osmogent and has ability to maintain stability of drug agent contained therein during delivery of the agent (col 10, line 15-55, col 11, line 5-30 and col 14, line 15-20). Furthermore, the capsule has expandable swellable plug in the mouth of the capsule (Figure 8) while the body portion

of the capsule also comprises expandable, swellable portion in parallel arrangement with thermo sensitive agent containing composition; that is relied upon by the examiner as an expandable barrier layer (fig 9 at col4, line 15-30). Al-Razzak et al. teach the use of the claimed anti-viral agents in combination with the claimed poly sorbates, such as polyoxyethylene (20) sorbitan monolaurate in a pharmaceutical formulation in a capsule form. See the abstract, column 2, and column 5, lines 30-44. The above reference teaches the claimed antiviral agents in combination with the claimed surfactants in a pharmaceutical formulation. It would have been obvious to a person skilled in the art by adjusting the amounts and types of fluid imbedding and retaining polymers, to achieve the instant dosage form configuration, considering that the patent '326 provide the teaching of the controlled release. See col 5, line 40-65, continuing to col 6, lines 1-8. One of ordinary skilled in the art would have been motivated to combine the disclosures in the prior art cited to make a drug delivery device for delivery of antiviral agents.

Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Applicant alleges criticality to the liquid anti-viral drug of the instant application in comparison with the microemulsion of Rudnic et al. Applicant is reminded that microemulsion is considered to be liquid as well. Furthermore, the secondary references teach the sustained release capsule form as claimed in claims 61-75.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Z.F
/Zohreh A Fay/
Primary Examiner, Art Unit 1612